AMENDMENTS TO THE SPECIFICATION

In the Specification

Please substitute the following amended paragraph(s) and/or section(s) (deleted matter is shown by strikethrough and added matter is shown by underlining):

Page 1, lines 4-12:

RELATED APPLICATIONS AND PRIORITY CLAIM

The present application is a continuation application of co-pending U.S. Patent Application No. 10/603,397, filed June 25, 2003, entitled "DYNAMIC BIOABSORBABLE FASTENER FOR USE IN WOUND CLOSURE,"[[,]] which is a Continuation-In-Part ~~Application~~ of U.S. Patent Application No. 10/179,628, filed June 25, 2002, now allowed as U.S. Patent No. 6,726,705, entitled, "MECHANICAL METHOD AND APPARATUS FOR BILATERAL TISSUE FASTENING,"[[,]] and co-pending U.S. Divisional Application No. 10/448,838, filed May 30, 2003, entitled "MECHANICAL METHOD AND APPARATUS FOR BILATERAL TISSUE FASTENING," all of which are herein incorporated by reference in their entirety.

Page 6, lines 12-22:

Second, if tissue is being retained as opposed to skewered, large amounts of subcuticular tissue must be retained by the fastener because subcuticular tissue tends to be elastic. Grabbing smaller volumes of tissue with a fastener might not [[i]]ensure that the tissue will be

approximated to achieve an efficacious closure. The fastener of the present invention accommodates this requirement without the need for an excessively large or excessively strong fastener. The fastener of the present invention utilizes two different types of tissue capture zones, a first larger initial tissue capture zone that can capture a sufficient amount of tissue when the fastener is deployed to counteract the initial elasticity of the tissue and still obtain an efficacious fastening. A second set of much smaller durable tissue retention zones within the cleats are then used to provide long term holding force while the main body of the fastener can dynamically reform in response to the lateral forces exerted by the tissue during the healing process.

Page 7, lines 1-12:

Finally, when fastening opposing sides of a wound, the opposing sides must be physically approximated during placement of the fastener. Once the opposing sides have been retainably fastened, the opposing sides tend to return to a more relaxed disposition during the healing process, thereby increasing lateral pressure on the bioabsorbable fastener. In conventional practice, the bioabsorbable fastener ends up being over-designed in order to assist in the initial approximation of the tissue that can result in a design that is more susceptible to failure as a result of the longer term lateral pressures applied during the wound healing process. In contrast, the bioabsorbable fastener of the present invention is designed for use with an insertion apparatus that mechanically approximates the opposing sides of wound tissue to insure the creation of consistent and repeatable pierced openings into which the fastener is positioned in a through-and-through manner to take advantage of elastically securing the tissue within the durable tissue

retention zones created by the cleats of the fastener.

Page 11, lines 8-16:

Due to the expense of bioresorbable polymer resins, it is preferable to avoid unnecessary waste during the molding process. In order to reduce waste, fastener 100 is preferably formed using a micromolding injection molding process. Micromolding injection molding is typically used when the molding shot size is less than 1 gram. Using an appropriate micromolding injection system, for example a Battenfeld Microsystem M50, resin waste can be significantly reduced during production of a fastener 100 in accordance with the present invention. In addition, a micromolding injection system has other processing advantages such as allowing high injection speeds to promote dimensional stability, low residence times at elevated temperatures and integrated part handling capabilities.

Page 12, lines 13-22 & Page 13, lines 1-9:

A preferred use of fastener 100 is in the subcuticular bilateral fastening of dermal tissue to close a skin wound 158, [[is]] depicted in Figs. 6 and 7, as well as in U.S. Patent Application No. 10/179,628 entitled, "Mechanical Method And Apparatus For Bilateral Tissue Fastening," and U.S. Patent Application No. 10/448,838, which is a divisional application also entitled "Mechanical Method And Apparatus For Bilateral Tissue Fastening," both of which are commonly assigned to the assignee of the present invention and are hereby incorporated by reference in their entirety. Skin wound 158 generally comprises a pair of opposing skin surfaces 160, 162 separated by a gap 164. Gap 164 can be created through either purposeful means, such

as a surgical incision, or accidental means such as an accidental cut. Opposing skin surfaces 160, 162 each comprise three distinct layers: an epidermal layer, or epidermis 166; a dermal layer, or dermis 168; and a subcuticular layer 170. The epidermis 166 comprises dead skin tissue that may hinder but does not assist in the biological healing process. The subcuticular layer 170 comprises a layer of fatty tissue typically lacking the strength necessary to anchor and hold skin closure fasteners throughout the biological healing process. Generally, a physician closes skin wound 158 by forcibly approximating the dermis 168 of opposing skin surfaces 160, 162. As the dermis 168 comprises living tissue, biological healing of skin wound 158 commences immediately upon approximation and limited healing occurs within the first 24 hours of approximation. In addition, the dermis 168 possesses enough strength and elasticity to anchor, hold and retain fastener 100.

Page 13, lines 20-22 & Page 14, lines 1-13:

In a preferred use of fastener 100, subcuticular bilateral fastening of dermal tissue present in wound 158 is accomplished using a through-and-through bilateral tissue fastening technique described in the concurrently filed U.S. Patent Application entitled "Mechanical Method And Apparatus For Bilateral Tissue Fastening," which is commonly assigned to the assignee of the present invention, a copy of which is attached and the disclosure of which is hereby incorporated by reference in its entirety. In this bilateral tissue fastening technique as shown, for example, in Fig. 8, fastener 100 is loaded between piercing members 174, 176 and backspan member 190. Cross-section 184 is designed to snugly accommodate exterior surface 112 such that only cleats 116, 118 protrude inwardly from cross-section 184. Once fastener 100 has been loaded, guide

member 192 is positioned within skin wound 158. Compression members 198, 200 are used to approximate opposing skin surfaces 160, 162 and force them within capture zones 194, 196. Compression members 198, 200 force skin wound 158 into an everted disposition 206 shown in Fig. 12. As will be apparent, delivery device 172 is capable of a variety of alternative embodiments including varying orientations of guide member 192, the incorporation of compression members 198, 200 into delivery device 172 and designs in which delivery device 172 includes storage and loading means allowing for a multi-shot design.

Page 17, lines 10-22 & Page 18, lines 1-14:

Depicted in Figs. 20 and 21, is fastener 100 in a generally open disposition 220 following exposure to lateral forces 216 exceeding those required to reform to semi-open disposition 218. Preferably, fastener 100 does not reform to generally open disposition 220 until a period of time T2 of at least ~~days~~ 1 to 14 days and optimally at least 7 days from insertion, though depending upon placement and wound location, reformation may occur immediately upon insertion. Fastener 100 is again reformed through polymer creep in shoulder regions 103, 105 and elbow regions 115, 117. It should be noted that the closure strength of fastener 100 decreases over time due to the breakdown of the bioabsorbable polymer by the human body. As such, lateral forces 216 which may not initially be enough to induce reforming of fastener 100, will likely induce at least some degree of fastener reforming at a time subsequent to placement of fastener 100 in wound 158. In generally open disposition 220, captured tissue remains approximated during the healing process as the elastic dermis continues to be retained within cleat bases 128. In general, cleat bases 128 will continue to retain the elastic dermis until the bioabsorbable polymer is

absorbed to a point where failure, such as a fracture of arms 102, 104 or backspan 106 occurs or polymeric creep in elbow regions 115, 177 results in elbow angle 142 opening beyond 90° such that the elastic dermis 168 slides off of cleats 128. In generally open disposition 220, shoulder angles 138 are increasingly difficult to distinguish and instead, an internal midspan angle 221 defined by a midpoint of the backspan 106 and the apex of each durable tissue retention zone 129, is created. In the preferred embodiment of subcuticular bilateral fastening of dermal tissue as depicted in Fig. 22, a pair of fasteners 100 that have reformed to generally open disposition 220 subsequent to insertion continue to approximate wound 158. Due to the continuing capture of the dermis 168 within cleat bases 128, wound 158 remains closed throughout the healing period, typically up to twenty-one (21) days. Throughout the reformation process, the sum of elbow angles 142 and the midspan angle remains less than 360° allowing fastener 100 to continually retain captured tissue beyond the minimum degradation period. Following minimum degradation period referred to as T3, fastener 100 is increasingly likely to suffer a fracture failure of the arms 102, 104, cleats 116, 118 or backspan 106.

Page 18, lines 15-22 & Page 19, lines 1-13:

While a preferred embodiment of fastener 100 and its method of use has been described, a variety of other staple configurations featuring the same dynamic reforming traits as well as through-and-through insertion method can be utilized. For example, Figs. 23, 24 and 25 depict alternative fastener designs incorporating additional retaining elements to further assist in wound closure. Depicted in Fig. 23, a fastener 222 comprises a backspan 224 and arms 226, 228. Arms 226, 228 include tips 230, 232 having a hammerhead orientation 234 including an internal cleat

236 and an external recess 238. Internal cleat 236 includes a cleat base 240 to similarly capture elastic tissue using the through-and-through insertion method. Depicted in Fig. 24, a fastener 242 comprises a backspan 244 and arms 246, 248. Arms 246, 248 include tips 250, 252 include an internal cleat 254 to similarly capture elastic tissue using the through-and-through method. In addition, arms 246, 248 include a series of internal projections 256 to further assist in retaining captured tissue as fastener 242 reforms in response to lateral forces supplied by captured tissue. Depicted in Fig. 25, a fastener 258 comprises a backspan 260 and arms 262, 264. Arms 262, 264 include tips 266, 268 having an internal cleat 270 to similarly capture elastic tissue using the through-and-through method. In addition, backspan 260 includes a pair of opposed projections 272, 274 to further assist in retaining captured tissue as fastener 258 reforms in response to lateral forces supplied by captured tissue. Although the fasteners of the present invention have been described with respect to an initial tissue capture zone that is defined by just two arms and within a single plane, it will be seen that a multiplicity of arms could be provided and that multiple planes could be accommodated for the tissue capture zone by, for example, making an angle in the backspan at the midpoint.

Page 20, lines 10-16:

Depicted in Fig. 29 is another alternative embodiment of a fastener 290. Fastener 290 comprises a backspan 292 and arms 294, 296. Fastener 290 included a thickness 297 that is generally consistent through backspan 292 and arms 294, 296. Arms 294, 296 further include tips 298, 300, each tip 298, 300 having an internal cleat 302 having a cleat base 304. Arms 294, 296 in combination with internal cleat 302 and cleat base 304 define a durable tissue retention

zone 306 to capture elastic tissue using the through-and-through insertion method as previously described.

Page 20, lines 17-22 & Page 21, lines 1-5:

In Figs. 30 and 31, there is shown an earlier embodiment of a fastener 400 of the present invention. Fastener 400 has body portion 402, which comprises a cross-member 408 connecting a pair of fork members or legs 406. The outer margins 410 of each leg 406 are dimensioned and shaped accommodatingly to the retaining space 186 of piercing members 174, 176, allowing fastener 400 to fit and slide between the piercing members 174, 176. Shoulders 414 preferably are provided to engage the solid cylindrical cross-section of the backspan member 190, thus allowing fastener 400 to be advanced distally with motion of the piercing members 174, 176. The distal end 412 of each leg 406 is incurvately shaped to allow easier passage through an opening in skin, referred to as a skive, that is created by piercing members 174, 176. Inwardly directed barbs 404 preferably are provided on each leg 406 to resist withdrawal of the fastener once emplaced.

Page 21, lines 6-17:

Although an overall U-shape for the fastener 400, as shown in Figs. 30 and 31 is preferred, other shapes having a capability for bilateral tissue engagement are also possible and within the scope of the invention. Such other shapes include for example, but are not limited to, a square shape similar to an ordinary staple, a semi-circular or C-shape or a V-shape or W-shape, in which the cross-member 408 has bends or other features. While the shape of fastener 400 is

generally determined in a planar configuration, it will be recognized that other non-planar shapes and configurations can be used, such as a fastener having multiple projections for each leg 406, with each projection oriented in a different plane, or a fastener having cross-member 408 arranged in a V-shape projecting out of the normal plane of the fastener 400. Two leg members 406 are preferred, but it will be understood that additional leg members 406 could be added in the same or a different plane of the fastener 400 such that the leg members of each side of the fastener form a dident or trident configuration, for example.